UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to:	)	
Deborah Johnson, No. 16-15607	)	
Barbara Earnest, No. 16-17144	)	
Tanya Francis, No. 16-17410	)	
Jacqueline Mills, No. 17-2689	)	

ORDER AND REASONS

Before the Court are six Motions for Summary Judgment. Three are based on statute of limitations defenses. One is against Deborah Johnson (Doc. 5734), one is against Barbara Earnest (Doc. 6079), and one is against Tanya Francis (Doc. 6081). The other three are based on the learned intermediary doctrine. One is against Jacqueline and Victor Mills (Doc. 5732), one is against Barbara Earnest (Doc. 6078), and one is against Tanya Francis (Doc. 6080).

For the following reasons, the Motions based on the statute of limitations against Johnson (Doc. 5734) and against Francis (Doc. 6081) are **GRANTED**, and the Motion based on the statute of limitations against Earnest (Doc. 6079) is **DENIED**. The Motions based on the learned intermediary doctrine against Mills (Doc. 5732) and against Earnest (Doc. 6078) are each **GRANTED IN PART** and **DENIED IN PART**. The Motion based on the learned intermediary doctrine against Francis (Doc. 6080) is **DISMISSED AS MOOT**.

GENERAL BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a

chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer and other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. Notably, in 2015, Taxotere manufacturers updated the drug's label to warn that cases of permanent hair loss have been reported as a side effect.

SUMMARY JUDGMENT STANDARD

Summary judgment is warranted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[2] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[3] Rule 56 of the Federal Rules of Civil Procedure "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[4]

I. Defendants' Motions Based on Prescription

a. Additional Background

According to the Master Complaint, Plaintiffs' injuries—disfiguring permanent alopecia—manifested six months after the completion of

[1] Docetaxel is the generic version of Taxotere.
[2] FED. R. CIV. P. 56.
[3] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[4] Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

chemotherapy.[5] The Master Complaint links these injuries to the Plaintiffs' cancer and chemotherapy, stating that "[a]lopecia symbolizes cancer identity and treatment."[6] Each of the three Plaintiffs here completed chemotherapy years before filing suit in 2016.[7] What prompted each Plaintiff to file suit was learning of the link between Taxotere and permanent hair loss. Plaintiff Johnson learned through a television advertisement, although when she saw this ad is unclear.[8] Plaintiff Earnest learned in 2016 through her brother who told her about lawyer advertisements for Taxotere lawsuits. Plaintiff Francis learned in 2016 through Facebook.

In these Motions, Defendants move for summary judgment against these Plaintiffs on the basis that their claims are time-barred under Louisiana prescription law. The Court heard oral argument on the Motion against Johnson on April 4, 2019 and on the Motions against Earnest and Francis on May 22, 2019.

b. The Parties' Arguments

Defendants argue that each Plaintiff was aware of her alleged injury six months after she completed chemotherapy. Defendants argue that this triggered the start of the prescriptive period for each Plaintiff and that she should have filed her complaint within a year after she became aware of her injury. Specifically, Defendants argue that summary judgment is warranted for three reasons: (1) the untimeliness of these cases is apparent from the pleadings; (2) discovery and deposition testimony confirms this untimeliness;

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[5] Second Amended Master Long Form Complaint ("AMC") (Doc. 4407) at ¶ 181.
[6] *See id.* at ¶ 6.
[7] Plaintiff Johnson completed chemotherapy in December 2010, Plaintiff Earnest completed chemotherapy in November 2011, and Plaintiff Francis completed chemotherapy in October 2009.
[8] She suggests that when she saw the ad is irrelevant and argues that her suit is timely because she filed it within one year of the Taxotere label change in 2015.

and (3) no exception applies to toll the statute of limitations and save Plaintiffs' cases.

Relying on the Louisiana doctrine of contra non valentem, Plaintiffs argue that the prescriptive period begins running only when a plaintiff has knowledge of the underlying tortious conduct of the defendant. Plaintiffs emphasize that during the relevant period the generally accepted medical and scientific belief known to Plaintiffs' physicians was that Taxotere could cause only temporary hair loss, not permanent hair loss. Plaintiffs note that as late as 2015, the Taxotere label did not mention permanent hair loss; yet, according to Defendants, Plaintiffs should have realized before then—before the Taxotere manufacturers knew—that the drug caused permanent hair loss.

c. Louisiana Prescription Law

Under Louisiana Civil Code Article 3492, the prescriptive period for products liability claims is one year.[9] Generally, the period begins to run from the day the injury or damage is sustained.[10] "If the face of the petition shows that the prescriptive period has already elapsed, the plaintiff has the burden of establishing that suspension, interruption or renunciation of prescription

[9] LA. CIV. CODE art. 3492. *See also In re:* Xarelto (Rivaroxaban) Prods. Liab. Litig., 2017 WL 4517287, *2 (E.D. La. Oct. 10, 2017).
[10] Carter v. Matrixx Initiatives, Inc., 391 Fed. App'x 343, 344 (5th Cir. 2010).

has occurred."[11] Because each Plaintiff's complaint is prescribed on its face,[12] Plaintiffs bear the burden of proof.

The doctrine of contra non valentem "provides some grace for those plaintiffs who are unaware that their injury was caused by a tort."[13] The doctrine states that prescription begins to run when a plaintiff has "actual or constructive knowledge of facts indicating to a reasonable person that he or she is the victim of a tort."[14] This occurs "when the plaintiff has actual or constructive knowledge of a causal relationship between the object or product and the injury."[15] "There is no requirement that a patient be informed by an attorney or physician of a possible [claim] before prescription begins to run."[16] Rather, prescription begins to run "when there is enough notice to call for an inquiry about a claim, not when an inquiry reveals the facts or evidence that specifically outline the claim."[17] "The ultimate issue is the reasonableness of

[11] Hoerner v. Wesley-Jensen, 684 So. 2d 508 (La. App. 4 Cir 1996).
[12] In the Master Complaint, Plaintiffs allege that their hair loss became permanent six months after the completion of chemotherapy. Each Plaintiff here completed chemotherapy years before filing suit, which was years after her injury was realized, according to the Master Complaint. Thus, each Plaintiff's complaint is prescribed on its face.
[13] *Xarelto*, 2017 WL 4517287 at *2.
[14] *Id.* (quoting *Bailey*, 891 So. 2d at 1276) (internal quotations omitted).
[15] *Id.*
[16] *Id.* (quoting Breaux v. Danek Med., No. 95-1730, 1999 WL 64929, at *6 (E.D. La. 1999)) (internal quotations omitted).
[17] Luckett v. Delta Airlines, Inc., 171 F.3d 295, 300 (5th Cir. 1999).

the [plaintiff's] action or inaction, in light of his education, intelligence, the severity of the symptoms, and the nature of the defendant's conduct."[18]

d. Analysis

i. Plaintiff Deborah Johnson

Plaintiff Johnson testified that she did not think anything other than her chemotherapy had caused her hair loss.[19] She finished her chemotherapy and radiation treatments in 2010, and she testified that as early as 2010, she became very concerned that her hair might not grow back at all.[20] Based on her testimony, Plaintiff had enough notice to call for an inquiry several years before she did. Perhaps as early as 2010 but no later than six months after she completed chemotherapy, she had "actual or constructive knowledge of a causal relationship between the object or product and the injury."[21]

Plaintiff, however, did not act until she saw a television ad describing the link between Taxotere and permanent hair loss. She did not consult counsel until after she saw the ad, and she did not file suit until October of 2016. The doctrine of contra non valentem does not suspend prescription for this kind of inaction. "It is not the rule in Louisiana . . . that the prescriptive period does not begin until conclusive dispositive proof of a causal connection between the suspected injury and the putative tortfeasor is established."[22]

Plaintiff relies on *Hoerner v. Wesley-Jensen*,[23] and the Court finds it distinguishable from Johnson's case. In *Hoerner*, the plaintiff suffered an eye

[18] Campo v. Correa, 828 So. 2d 502, 511 (La. 2002).
[19] Doc. 5734-5 (p. 307).
[20] *Id.* (pp. 307–09).
[21] *See Xarelto*, 2017 WL 4517287 at *2.
[22] *Carter*, 391 Fed. App'x at 345–46.
[23] 684 So. 2d 508 (La. App. 4 Cir. 1996).

infection and alleged it was from extended-wear contacts.[24] She had used the contacts in 1987 for six months before developing the severe infection, for which she received immediate treatment.[25] Unlike in the instant case, the *Hoerner* plaintiff asked her doctor about the cause of her injury, and he told her it was some kind of "bug" she caught.[26] In 1989, however, she read an article and learned that extended-wear contacts present a significant risk of severe eye infections.[27] She filed suit weeks later.[28] Applying contra non valentem, the court deemed her inaction reasonable:

> Not until Mrs. Hoerner read in the popular press in 1989 that users of extended-wear contact lenses were more likely to contract eye infections than those using daily-wear lenses did she suspect that she had been injured by another's conduct, rather than by a "bug" to which anyone could have been exposed.[29]

Unlike the plaintiff in *Hoerner*, Johnson has presented no evidence demonstrating that she investigated her injury. Nor has she presented evidence to show that, like the plaintiff in *Hoerner*, she relied on information she discovered from such an investigation.

Because Johnson had a duty to investigate and failed to do so, contra non valentem is inapplicable to her claims. Johnson completed her chemotherapy

[24] *Id.* at 509.
[25] *Id.*
[26] *Id.* at 514.
[27] *Id.* at 509.
[28] *Id.*
[29] *Id.* at 514.

in December 2010, meaning her injury was realized six months later in June 2011. Her claims prescribed no later than June 2012.

ii. Plaintiff Barbara Earnest

Like Johnson, Earnest testified that she attributed her hair loss to her chemotherapy treatment.[30] Six months after completing her chemotherapy, she became concerned that her hair had not grown back as expected, prompting her to ask her oncologist, Dr. James Carinder, about her hair loss.[31] Earnest testified about this discussion as follows:

> Q. And what is your recollection of what Dr. Carinder told you?
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> A. That it's going to come back. It just takes time. So I just kept waiting.[32]

Earnest's testimony distinguishes her case from Johnson's case. Like the plaintiff in *Hoerner*, Earnest inquired with her doctor about her injury, and she was led to believe that she had no actionable injury. Relying on her doctor's statements, she acted reasonably in waiting and remaining hopeful for her hair to return. When she learned in 2016 of the association between Taxotere and permanent hair loss, she realized that, contrary to what she initially thought, she did have an actionable injury.

Defendants argue that Earnest was in possession of information years earlier that should have put her on notice of the connection between Taxotere and permanent hair loss. Earnest's surgeon, Dr. Marie Celeste Lagarde, gave Earnest a handbook when she was first diagnosed with breast cancer, and as a side effect of Taxotere, the handbook listed "rare reports of permanent hair

[30] Doc. 6079-4 (p. 83).
[31] *Id.* (p. 82).
[32] *Id.*

loss."[33] Dr. Lagarde testified, however, that she would have only directed Earnest to two sections of the handbook—the section covering pathology reports and the section covering the pros and cons of a lumpectomy versus a mastectomy.[34] Dr. Lagarde specifically testified that at the time she gave Earnest the handbook, she did not know whether Earnest would be administered Taxotere or a different chemotherapy drug.[35] This Court finds that Earnest was not unreasonable in failing to review the handbook cover to cover and apprise herself of the risks of a drug she may not even take.

Because Earnest investigated her injury and was led to believe she had no actionable injury, contra non valentem is applicable. Accordingly, the prescriptive period on Earnest's claim did not begin to run until she associated Taxotere with permanent alopecia in 2016. Because Earnest filed suit within a year of this realization, her claim is not prescribed.

iii. Plaintiff Tanya Francis

Like Johnson and Earnest, Francis attributed her hair loss to her chemotherapy, which she completed in October of 2009.[36] Francis testified that six months later her hair began to regrow, but it grew back thinner and with a different texture.[37] Her Plaintiff Fact Sheet reports that she sustained her injury at the age of 38, which was her age during her treatment in 2009.[38] For years after this, Francis knew her hair had not returned as expected, yet she never investigated. She argues that even if she had, her investigation would have been futile. However, under the doctrine of contra non valentem, "[t]he

[33] Doc. 6079 at 9.
[34] Doc. 6611 at 10.
[35] *Id.*
[36] Doc. 6081-4 at 4, 6 (pp. 192, 221).
[37] *Id.* at 7 (p. 222).
[38] *See* Tanya Francis Plaintiff Fact Sheet § I.15, ¶ IV.2.

ultimate issue is the reasonableness of the [plaintiff's] action or inaction, in light of his education, intelligence, the severity of the symptoms, and the nature of the defendant's conduct."[39] Francis's allegations make clear that she recognized the severity of her symptoms and that she attributed her hair loss to her chemotherapy. This should have prompted her to investigate.

Francis argues that contra non valentem should apply because she had no way of determining that her hair loss was attributable to Taxotere rather than one of the other chemotherapy drugs she took. This argument falls flat because Francis made no effort to investigate her injury or to identify which drug and which manufacturer was responsible for her injury. "[W]hen a plaintiff suspects something is wrong, he must seek out those whom he believes may be responsible for the specific injury."[40] The court ruled that only "when a plaintiff acts reasonably to discover the cause of a problem" does the prescriptive period toll "until [he has] a reasonable basis to pursue a claim against a specific defendant."[41]

Because Francis had a duty to investigate and failed to do so, contra non valentem is inapplicable to her claims. Francis completed chemotherapy in October 2009, meaning her injury was realized six months later in April 2010. Her claims prescribed no later than April 2011.

II. Motions Based on Learned Intermediary Doctrine

a. Additional Background

Plaintiffs in the Mills case are Jacqueline Mills and Victor Mills. Plaintiffs assert eight counts under Georgia law: (I) strict products liability for failure to warn; (II) strict products liability for misrepresentation; (III)

[39] *Campo*, 828 So. 2d at 511.
[40] Chevron USA, Inc. v. Aker Maritime, Inc., 604 F.3d 888, 894 (5th Cir. 2010).
[41] *Id.*

negligence; (IV) negligent misrepresentation; (V) fraudulent misrepresentation; (VI) fraudulent concealment; (VII) fraud and deceit; and (VIII) breach of express warranty. Counts II and VIII were dismissed under Pretrial Orders 61 and 73. In the Motion against the Mills Plaintiffs, Defendants move for summary judgment on all remaining claims brought by Plaintiffs. Defendants argue that Plaintiffs cannot establish the essential element of causation. The Court heard oral argument on the Motion against Mills on April 4, 2019.

Plaintiffs Barbara Earnest and Tanya Francis each assert two claims under Louisiana law: (1) a claim that Defendants provided an inadequate warning in violation of the Louisiana Products Liability Act; and (2) a claim for breach of warranty in redhibition. In their Motions against Earnest and Francis, Defendants move for summary judgment, arguing that the learned intermediary doctrine is dispositive of both the inadequate warning claims and the redhibition claims. Alternatively, Defendants argue that Plaintiffs have no redhibition claims because Taxotere had no defect rendering it useless. The Court heard oral argument on these Motions on May 22, 2019.

b. Plaintiffs Jacqueline and Victor Mills

i. Claims for Failure to Warn and Negligence

Defendants first argue that under Georgia law they are entitled to summary judgment on Plaintiffs' failure to warn and negligence claims. Relying on the learned intermediary doctrine, they argue that Plaintiffs have failed to introduce evidence that a different warning from Defendants would have led Jacqueline Mills's oncologist, Dr. Shefali Shah, to change her decision to prescribe medication containing Taxotere/docetaxel. In other words, Defendants argue that the causation chain is broken due to Dr. Shah's actions

as an intermediary. Defendants note that Dr. Shah "testified that a label change would not have affected her decision to prescribe the life-saving TCH chemotherapy regimen to Plaintiff because the regimen remains the 'standard of care in this setting.'"[42]

Plaintiffs agree that the Georgia learned intermediary doctrine bears on cases involving prescription drug manufacturers. Plaintiffs argue, however, that this case presents triable issues of fact for a jury to assess. Plaintiffs argue that the adequacy of Defendants' warning is a question for the jury, as is whether Dr. Shah would have taken a different course of action if Defendants had warned her of the increased risk of permanent hair loss associated with Taxotere/docetaxel. Plaintiffs note that Dr. Shah testified that "she would have respected her patient's wishes, had she expressed a desire to try an alternative treatment to avoid the risk of permanent hair loss."[43]

Under Georgia law, a failure to warn claim has three elements: (1) the defendant had a duty to warn; (2) the defendant breached that duty; and (3) the breach was the proximate cause of the plaintiff's injury.[44] The proximate cause element is the focus of Defendants' Motion. Like a failure to warn claim, a Georgia negligence claim requires a showing of proximate cause.[45] If Defendants, therefore, can show that Plaintiffs would have taken Taxotere regardless of Defendants' conduct, Plaintiffs cannot prove causation for their failure to warn or negligence claims.[46]

In cases involving prescription drugs, Georgia courts employ the learned intermediary doctrine, "which alters the general rule that imposes liability on

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[42] Doc. 5732-2 at 8.
[43] Doc. 6347 at 11.
[44] Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1362 (S.D. Ga. 1999).
[45] Porter v. Eli Lilly & Co., No. 1:06-1297, 2008 WL 544739, at *9 (N.D. Ga. Feb. 25, 2008).
[46] *See Porter*, 2008 WL 544739 at *5–13 (applying the learned intermediary doctrine and holding that plaintiff could not establish proximate cause for failure to warn or negligence

a manufacturer for failing to warn an end user of the known risks or hazards of its products."[47] Pursuant to the doctrine, a manufacturer of prescription drugs does not have a duty to directly warn the patient but instead has only a duty to warn the patient's doctor.[48] "The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication . . . involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities."[49]

Under this doctrine, a threshold inquiry is whether the manufacturer provided the learned intermediary, the physician, with an adequate warning.[50] If the warning was adequate, the inquiry ends, and the plaintiff cannot recover.[51] If the warning was inadequate, or presumed to be, the plaintiff must show that the inadequate warning proximately caused the alleged injury to occur.[52] "Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that . . . the causal link is broken and the plaintiff cannot recover."[53] Accordingly, if a treating physician testifies that he was aware of the risks associated with a product, that such risks were well known in the medical community, and that he would have taken the same course of action

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claims); Gen. Motors Corp. v. Davis, 141 Ga. App. 495, 496 (1977) ("The defendant's conduct is not a cause of the event, if the event would have occurred without it.") (internal quotations and citations omitted).

[47] Dietz v. Smithkline Beecham Corp., 598 F. 3d 812, 815 (11th Cir. 2010) (citing *Wheat*, 46 F. Supp. 2d at 1363).

[48] *Id.*

[49] McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003) (internal citations and quotation marks omitted).

[50] *Dietz*, 598 F.3d at 815 (citing *Wheat*, 46 F. Supp. 2d at 1363).

[51] *Id.* (citing Singleton v. Airco, Inc., 314 S.E.2d 680, 682 (Ga. Ct. App. 1984)).

[52] *Id.* (citing *Wheat*, 46 F.Supp.2d at 1363).

[53] *Wheat*, 46 F. Supp. 2d at 1363.

in spite of the information that a plaintiff contends should have been provided, summary judgment is warranted.[54]

Regarding the adequacy of Defendants' warning, Plaintiffs in this MDL allege that from the time of Taxotere's FDA approval in 1996 through December of 2015, Taxotere's label contained no reference or warning regarding permanent hair loss.[55] In addition to this, Dr. Shah testified that when she treated Ms. Mills, she did not know that Taxotere/docetaxel had a higher risk of permanent hair loss than other drugs.[56] Therefore, for purposes of this Motion, the Court presumes that the label was inadequate at the time of Ms. Mills's treatment.

The next step in the inquiry is whether the inadequate warning proximately caused Ms. Mills's permanent hair loss. Defendants argue that Plaintiffs have no evidence that "a different warning would have resulted in a different prescribing decision."[57] Defendants rely on *Porter v. Eli Lilly and Co.* [58] In *Porter*, the plaintiff sued the manufacturer of a prescription antidepressant, Prozac.[59] The plaintiff alleged, after her husband's suicide, that the manufacturer failed to adequately warn of the risks of suicide associated with the drug.[60] The prescribing physician, however, testified that he would only have discussed suicide risks with the decedent if he had determined him to be a suicide risk.[61] The court wrote that "no matter what might have been presented as a warning with Prozac in terms of increased

[54] *See id.* at 1364.
[55] Doc. 6347 at 2 (citing Second Am. Master Compl. at ¶¶ 124–38).
[56] *Id.* at 14.
[57] Doc. 5732-2 at 1.
[58] 2008 WL 544739 (N.D. Ga. Feb. 25, 2008).
[59] *Id.* at *1.
[60] *Id.*
[61] *Id.* at *12.

suicide risk, this would not have impacted Dr. Wolfberg's decision-making because he did not view Mr. Porter as a suicide risk."[62]

The decision to prescribe an antidepressant differs from the decision to prescribe chemotherapy. As illustrated by the testimony of these Plaintiffs and their oncologists, a patient facing a cancer diagnosis can reasonably expect more involvement and guidance from her doctor than she would in another context. A cancer patient looks to her oncologist to educate her about what options are available, what serious side effects she will likely suffer, and how she can prepare for those side effects.[63] Cancer treatment is patient-driven, and doctors seek input from their patients and ultimately require them to execute an "informed consent" certification.[64] The decision-making process, therefore, is typically a thorough, back-and-forth dialogue between a doctor and her patient, likely occurring over the course of several appointments. During such a dialogue, a doctor considers and addresses any concerns expressed by the patient.[65] In sum, the conversation between a doctor and a cancer patient is more robust than the conversation between a doctor and a

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[62] *Id.*

[63] *See, e.g.*, Doc. 6753-4 at 29–30 (pp. 108–12) (deposition of Barbara Earnest) (testifying that she would rely on her doctor in weighing her options and that she would have wanted to know about the severity, likelihood, and permanence of any side effects associated with a drug); Doc. 6755-3 at 25 (p. 92) (deposition of Dr. Cherian Verghese) (testifying that he has a "comprehensive discussion" with patients and explains "what the common side effects are, what the outcomes are, and I also have to go through other things like the payment issue, insurance issue"); *id.* at 26 (p. 94) (testifying that he talks to patients "about individual drugs and the problems from individual drugs" as well as "problems from combination drugs, because the risks from combinations are different from risk of individual drugs").

[64] *See e.g.*, Doc. 6347-3 at 374 (p. 43) (deposition of Dr. Shefali Shah) (introducing "informed consent" as exhibit); Doc. 6753-4 at 10 (p. 30-32) (deposition of Barbara Earnest) (discussing consent document by which Earnest "provided consent to chemotherapy and the risks associated with the chemotherapy").

[65] *See e.g.*, Doc. 6755-3 at 13 (p. 42) (deposition of Dr. Cherian Verghese) ("If a patient has a concern and if the -- if there's a way of improving the outcome and keeping the patient's concern valid, yes, I look for options.").

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patient struggling with a non-life-threatening ailment, when treatment options often have less debilitating side effects.

Because the chemotherapy decision-making process is unique, the application of the learned intermediary analysis in this context is not as simple as Defendants suggest. The question is not simply "what would the doctor have prescribed" but whether and how the doctor would have advised the patient of the risk of permanent alopecia associated with Taxotere, whether the patient would have inquired about other options, what the doctor would have recommended, and what decision the plaintiff would have ultimately made. The Court will consider these questions with the goal being to assess what the doctor and the patient would have decided together. While a doctor may testify that his or her recommendation would not have changed, the issue is whether the plaintiff's ultimate decision would have changed.

In the Mills's case, the evidence is sufficient to create an issue of fact on whether Ms. Mills and Dr. Shah would have decided on a non-Taxotere regimen for her treatment if Dr. Shah had been adequately warned by Defendants. At her deposition in 2018, Dr. Shah testified that she had recently become aware of the risk of permanent alopecia associated with Taxotere.[66] When asked whether she would have shared this information with Ms. Mills years ago, she testified, "I presume so."[67] When asked if this is something she would counsel her patients about, she testified, "Yes, I think so."[68]

Although Dr. Shah testified that she has no doubt in her mind that the regimen she prescribed to Ms. Mills was the right choice for Mills's aggressive form of cancer,[69] she also testified as follows: "I tell my patients, you know, my

[66] Doc. 6347-3 at 428 (p. 97).
[67] *Id.* at 421 (p. 90).
[68] *Id.* at 422 (p. 91).
[69] *Id.* at 347–50 (pp. 16–19).

job is to give you my recommendations as a physician and alternatives, you know, but I respect every patient's authority over themselves. It's their body. It's their life."[70]

In addition to this, testimony from Ms. Mills creates an issue of fact on whether she would have followed the recommendation of Dr. Shah. The evidence suggests that Ms. Mills was very involved in this decision-making process. At some point during her treatment, Ms. Mills complained to Dr. Shah of her side effects, and Dr. Shah mentioned that Ms. Mills could reduce her dosage.[71] Although her dosage was never changed,[72] Ms. Mills ultimately decided to forgo her last infusion due to the side effects.[73] Further, Ms. Mills testified that she chose a lumpectomy over a mastectomy.[74] She testified that she did not want to appear one-sided.[75] These facts suggest that Ms. Mills did not blindly follow the advice of her doctor, that in making her healthcare decisions she considered her appearance, and that she may have selected less aggressive treatment if it meant protecting her appearance or quality of life.

Considering the testimony of both Dr. Shah and Ms. Mills, the Court finds an issue of fact on whether the causation chain is broken here. There is an issue of fact on whether Dr. Shah would have warned Ms. Mills of the risk of permanent hair loss associated with Taxotere, and there is an issue of fact

[70] *Id.* at 379 (p. 48).
[71] *Id.* at 172–73 (pp. 149–50).
[72] *Id.*
[73] *Id.* at 173–74 (pp. 150–51).
[74] *Id.* at 93 (p. 70).
[75] *Id.* at 95 (p. 72).

on whether Ms. Mills would have ultimately chosen to take Taxotere if she had known of this risk.

ii. Additional Claims Brought by Mills Plaintiffs

Defendants argue that Georgia law does not recognize a distinction between a failure to warn claim and a misrepresentation claim. In their response, Plaintiffs state that they do not intend to continue pursuing Count IV for negligent misrepresentation and Count V for fraudulent misrepresentation. Accordingly, these claims are dismissed.

Defendants further argue that the learned intermediary doctrine requires the dismissal of Plaintiffs' remaining claims—Count VI for fraudulent concealment and Count VII for fraud and deceit. For the same reasons the learned intermediary doctrine does not warrant summary judgment on Plaintiffs' negligence and failure to warn claims, the doctrine does not warrant summary judgment on Plaintiffs' remaining claims.

Defendants raise an alternative argument for the dismissal of Plaintiffs' fraud-based claims. Defendants argue that Plaintiffs have no evidence of two essential elements of these claims—namely, a misrepresentation by Defendants and Plaintiffs' reliance on such a representation.

Under Georgia law, a fraud claim has five elements: (1) a false representation by the defendant; (2) scienter; (3) intention to induce the plaintiff to act or refrain from acting; (4) justifiable reliance by the plaintiff; and (5) damage to the plaintiff.[76] The parties agree that, in the instant case, the inquiry is whether Defendants made a false representation to Dr. Shah and whether Dr. Shah relied on this. Defendants aver that Plaintiffs point to no statement provided to Dr. Shah that was false and made with the intent to

[76] Brazil v. Janssen Research & Dev. LLC, 249 F. Supp. 3d 1321, 1339 (N.D. Ga. 2016).

induce Dr. Shah to refrain from acting. Defendants further aver that there is no evidence that Dr. Shah relied on any such statement from Defendants.

The Court rejects Defendants' argument. Defendants made express statements to Dr. Shah through Taxotere's label. In their Motion, Defendants admit that while the Taxotere label has since its inception warned of hair loss, it did not warn of *permanent* hair loss until December of 2015.[77] Further, Dr. Shah's testimony provides evidence tending to show that she did rely on Defendants' representation. In reliance on the Taxotere/docetaxel label, she did not warn her patient, Ms. Mills, of permanent hair loss. Accordingly, Plaintiffs have created an issue of fact on their fraud-based claims.

c. Plaintiffs Barbara Earnest and Tanya Francis

i. Failure to Warn Claims

Regarding Plaintiffs' Earnest and Francis, Defendants rely on the Louisiana learned intermediary doctrine, arguing that an adequate warning from Defendants would have been futile. They argue that because the doctors of these Plaintiffs did not read the Taxotere labeling, these doctors would have prescribed Taxotere regardless of whether the label warned of the risk of permanent hair loss. Plaintiffs argue that these doctors stayed informed of updates to the label through other means.

Under Louisiana law, failure to warn claims involving prescription drugs are subject to the learned intermediary doctrine.[78] Under the doctrine, the manufacturer of a prescription drug "has no duty to warn the patient, but need

[77] Doc. 5732-2 at 2.
[78] Grenier v. Med. Eng'g Corp., 99 F. Supp. 2d 759, 765 (W.D. La. 2000) (applying Louisiana law), *aff'd*, 243 F.3d 200 (5th Cir. 2001).

only warn the patient's physician."[79] In other words, a manufacturer's duty runs only to the physician—the learned intermediary.[80]

The Fifth Circuit has held that there is a two-prong test governing inadequate warning claims under the Louisiana Products Liability Act (LPLA) when the learned intermediary doctrine is applicable:

> First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.[81]

Regarding the second prong, the law is well established that, to prove causation, "the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product."[82]

As the Court has discussed, the chemotherapy decision-making process is unique. The Court must consider not only whether an oncologist would have warned his or her patient of the risk of permanent alopecia but also how patient choice then would have steered the conversation and the ultimate prescribing decision. For Plaintiff Earnest, the evidence is sufficient to create an issue of fact on whether she and her doctor, Dr. James Carinder, would have decided on a Taxotere regimen regardless of the risk of permanent alopecia.

Dr. Carinder testified that at the time Earnest was treated, he had two drugs he could choose from for her treatment—docetaxel or paclitaxel.[83] Both

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[79] Willett v. Baxter Intern., Inc., 929 F.2d 1094, 1098 (5th Cir. 1991).
[80] *Grenier*, 99 F. Supp. 2d at 766.
[81] Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 265–66 (5th Cir. 2002) (internal citation omitted).
[82] *Willett*, 929 F.2d at 1099. *See also* Pellegrin v. C.R. Bard, 2018 WL 3046570, at *4 (E.D. La. June 20, 2018).
[83] Doc. 6753-3 at 8 (p. 25).

drugs had equivocal efficacy.[84] Dr. Carinder testified that when he started his practice, "paclitaxel was the only thing that was really coming around" and "everybody was using that."[85] When docetaxel "came along," Dr. Carinder tended to choose that over paclitaxel.[86] He testified that "the reason I gravitated more towards using docetaxel is because you didn't lose efficacy, but you reduced the infusion-related complications and the daunting neuropathy that a lot of patients get."[87]

Earnest testified that if she had the option of taking a drug other than Taxotere/docetaxel, she would have relied on Dr. Carinder to make sure this drug would be as effective as Taxotere.[88] She testified that she would have wanted to know the side effects of the drug, including the severity, likelihood, and permanence of those side effects.[89] If the alternative drug carried a risk of neuropathy, this potentially would have influenced her decision.[90] She testified that she suffers from neuropathy and that it is very painful.[91]

The testimony from Dr. Carinder and Earnest creates an issue of fact. The testimony shows that Earnest had a viable alternative to Taxotere. The jury will need to hear the testimony at trial and decide whether Earnest would have chosen paclitaxel despite her neuropathy or whether she would have still chosen Taxotere knowing of its risk of permanent alopecia.

Although the Court is dismissing Plaintiff Francis's claim as prescribed, the Court notes that she could have defeated Defendants' summary judgment motion on causation. Testimony from her oncologist, Dr. Cherian Verghese,

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[84] *Id.* at 9 (p. 26).
[85] Doc. 6078-5 at 5 (p. 69).
[86] *Id.* (p. 69).
[87] *Id.* (p. 69).
[88] Doc. 6753-4 at 29 (pp. 108–09).
[89] *Id.* (p. 109).
[90] *Id.* at 30 (pp. 111–12).
[91] *Id.* (pp. 110–12).

suggests that, had Defendants issued a proper warning, Dr. Verghese would have learned of it and advised Francis of it. He testified that he learned of the association between Taxotere and permanent alopecia through literature and case reports.[92] When asked if he looked specifically for this information, he said no, explaining that because the Taxotere regimen is "a very common regimen," an update on the risk of permanent alopecia associated with it "would come out somewhere where we -- where it's more visible."[93]

Dr. Verghese testified that after learning about the potential risk of permanent hair loss associated with Taxotere, he began to educate his patients about this risk.[94] He tells his patients that Taxotere/docetaxel can cause permanent hair loss, and while there are no reports of permanent hair loss associated with Taxol/paclitaxel, "[t]hat doesn't mean it won't [cause permanent hair loss]."[95] More specifically, Dr. Verghese testified that if he had been made aware that Taxotere carried a risk of permanent alopecia in 2009, he would have discussed this with Francis because "[w]omen are very concerned about hair loss."[96]

Dr. Verghese testified that he has a "comprehensive discussion" with a patient facing chemotherapy.[97] He explained that "we go one by one and tell them what -- what their chances are of having that side effect, and then we ask them if there are the side effects that they are concerned about, which they sometimes have, because they also have been reading about it."[98] He talks to patients "about individual drugs and the problems from individual drugs" as

[92] Doc. 6755-3 at 29 (p. 107).
[93] *Id.* (p. 108).
[94] *Id.* at 30 (p. 110).
[95] *Id.* (p. 110).
[96] *Id.* at 33 (p. 122).
[97] *Id.* at 25 (p. 92).
[98] *Id.* (p. 91).

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well as "problems from combination drugs, because the risks from combinations are different from risk of individual drugs."[99] He testified that if a patient expresses concern about a particular side effect, he looks for other options: "If the patient has a concern and if the -- if there's a way of improving the outcome and keeping the patient's concern valid, yes, I look for options."[100] He further testified that "[h]air loss is a common side effect, which always gets into the discussion."[101] Either he or the patient will raise the subject.[102]

In addition to this, testimony from Francis suggests that her input in the decision-making process may have led Dr. Verghese to prescribe a non-Taxotere regimen for her. Francis played an active role in her healthcare. She testified that she did her own research on the chemotherapy drugs that her doctor recommended. In her deposition, she stated, "I stayed on a computer through the whole process of me having breast cancer, just finding out any and everything. Whatever they told me, I went and researched it myself, as well."[103] She is mindful of what drugs she is taking and pays careful attention to the side effects that are associated with those drugs.[104] She testified that she researched the side effects of Taxotere and other drugs specifically:

> I just Googled and went online and just typed in the medicines, Taxotere. They gave me the class of drug that it was, what it was treated for, the other name for it. I can't remember. Side effects. The same with Cytoxan. It gave me another name, C-H-O-Y, a

[99] *Id.* at 26 (p.94).
[100] *Id.* at 13 (p. 42).
[101] *Id.* at 26 (pp. 96–97).
[102] *Id.* (p. 97).
[103] Doc. 6755-4 at 76.
[104] *Id.* at 53 (pp. 56–57) ("I did research for the tamoxifen, and I know that tamoxifen was supposed to put me in menopause. It also causes, I think thickness in the lining of the uterus, but ARIMIDEX – the ARIMIDEX is just with the bones."); *id.* at 54 (p. 61) (explaining that when she is prescribed a new medication, she reviews the label, stating "I'd open up the bag, just picking up the prescription from the pharmacy, tear the pamphlet off and I would just look at it.").

> whole long – a long name, what it was treated for, the class of drugs. Adriamycin, the same thing. That was basically it.

She reviewed the pamphlets that she received from the hospital, and she remembers that the pamphlets warned of temporary hair loss.[105]

Francis further testified that before starting her chemotherapy treatment, she attended a program at her hospital called "Look Good, Feel Better."[106] She described it as "a little session where you meet with a group of women that had breast cancer or any kind of cancer, I guess, makeup tips, hair tips, give you places where you can go and purchase scarves, wigs."[107] This suggests that Francis was concerned about the hair loss she would experience. She further testified that while she trusted Dr. Verghese, if he were to make the same recommendation to her today, she would seek a second opinion and ask him to do research on other medications.[108] She stated as follows:

> He's my doctor. He's only here to give me advice and suggestions, but it's based on me to make the decision. And I would suggest that he find another regimen for me, and if he won't, I will go to someone else.[109]

Taken together, the testimony of Dr. Verghese and Francis show that had Defendants adequately warned of the risk of permanent hair loss associated

[105] *Id.* at 111 (pp. 180–81) (explaining that she picked up pamphlets in the waiting room and that the Taxotere pamphlet referenced temporary hair loss); *id.* at 118–19 (p. 208–09) (explaining that on the day of her first chemotherapy treatment, her nurse gave her printouts about each drug and Francis recalled that the Taxotere printout warned of temporary hair loss).
[106] *Id.* at 117 (pp. 202–03).
[107] *Id.* (p. 202).
[108] *Id.* at 138 (p. 287).
[109] *Id.* (p. 289).

with Taxotere, Dr. Verghese and Francis may have decided on a different drug for Francis. This would have been a question for the jury.

ii. Redhibition Claims

Defendants argue that they are entitled to summary judgment on Earnest's and Francis's redhibition claims. Article 2520 of the Louisiana Civil Code provides that a defect is redhibitory if it "renders the thing useless" or renders its use "so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect."[110] If a defect does not render the thing totally useless, it may still be redhibitory if the defect "diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price."[111] To determine whether a defect is redhibitory, a court asks whether a reasonable person would still have purchased the thing if he had known of the defect.[112] "It is of no moment that the plaintiff buyer who files suit to rescind a sale testifies that he would not have purchased the thing if he would have known of the vice."[113]

Plaintiffs took Taxotere to increase their chances of survival. Given that Plaintiffs are alive today, Taxotere worked and was far from being "useless." Indeed, Plaintiffs' doctors still prescribe Taxotere today. Dr. Carinder testified that the drug is effective, and he continues to prescribe it today "because it works."[114] He even called it "a good drug."[115] Dr. Verghese testified that the regimen Francis used is still an approved treatment regimen in the medical

[110] LA. CIV. CODE art. 2520.
[111] *Id.*
[112] Napoli v. Gully, 509 So. 2d 798, 799 (La. App. 1st Cir. 1987).
[113] *Id.*
[114] Doc. 6078-5 at 19–20 (pp. 127–28).
[115] *Id.* at 20 (p. 128).

community today.[116] He testified that he still recommends it to patients.[117] One of Plaintiffs' experts, Dr. Linda Bosserman, testified that Taxotere has contributed to saving lives.[118] Because Taxotere is demonstrably effective and worked as intended, Plaintiffs cannot establish a redhibitory defect.[119]

CONCLUSION

Accordingly, for the foregoing reasons, **IT IS ORDERED** that:

- Defendants' Motion for Summary Judgment Based on the Statute of Limitations Against Deborah Johnson (Doc. 5734) is **GRANTED**. This case is **DISMISSED WITH PREJUDICE**;
- Defendants' Motion for Summary Judgment Based on the Statute of Limitations Against Tanya Francis (Doc. 6081) is **GRANTED**. This case is **DISMISSED WITH PREJUDICE**;
- Defendants' Motion for Summary Judgement Judgment Based on the Statute of Limitations Against Barbara Earnest (Doc. 6079) is **DENIED**;
- Defendants' Motion for Summary Judgment on Causation Against Jacqueline and Victor Mills (Doc. 5732) is **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs' claims for negligent misrepresentation and fraudulent misrepresentation are **DISMISSED WITH PREJUDICE**. Their other claims remain pending;

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[116] Doc. 6755-3 at 38 (p. 145).
[117] *Id.* at 38–39 (pp. 145–46).
[118] Doc. 6078-10 at 5 (p. 536).

> Q: You certainly would agree that it's possible that these three women are here and alive today because they received systemic treatment for their cancer that included Taxotere?
>
> A: Yes, I would agree to that statement.

[119] *E.g.*, *In re* Rezulin Prods. Liab. Litig., 361 F.Supp.2d 268, 280 (S.D.N.Y. 2005) (granting defendant summary judgment in MDL case applying Louisiana law where plaintiffs could not demonstrate a redhibitory defect in a prescription medication because the drug was effective in treating the condition it was designed to treat).

- Defendants' Motion for Summary Judgment on Causation Against Barbara Earnest (Doc. 6078) is **GRANTED IN PART** and **DENIED IN PART**. Her redhibition claims are **DISMISSED WITH PREJUDICE**. Her other claims remain pending; and
- Defendants' Motion for Summary Judgment on Causation Against Tanya Francis (Doc. 6080) is **DISMISSED AS MOOT**.

New Orleans, Louisiana this 9th day of July, 2019.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE